K082005

AUG 25 2008

Section 4 510(k) Safety and Effectiveness Summary

4.1 General Information

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

Contact Person:	Robert Bovy TomoTherapy, Inc. 1240 Deming Way Madison, WI 53717-1954
Phone:	(608) 824-2938
Fax:	(608) 830-3771
Date:	July 7, 2008
Device Trade Name:	HI-ART System (modified)
Common Name:	Radiation Therapy System
Classification Name:	Medical Charged Particle Radiation Therapy System
Predicate Devices:	TomoTherapy Hi-Art System K060912
	Varian Clinac 600 K926321

4.2 Intended Use

The TomoTherapy HI-ART System is intended to be used as an integrated system for the planning and precise delivery of radiation therapy, stereotactic radiotherapy, or stereotactic radiosurgery to tumors or other targeted tissues while minimizing the delivery of radiation to vital healthy tissue. The megavoltage x-ray radiation is delivered in a rotational, non-rotational, modulated (IMRT), or non modulated (non-IMRT/three dimensional conformal) format in accordance with the physician approved plan.

4.3 Description

The TomoTherapy HI-ART System is a radiation therapy system that integrates planning, dose calculation, megavoltage CT scanning for IGRT functionality, and helical radiation therapy treatment capabilities into a single comprehensive system. The megavoltage CT image is not for diagnostic use. This modification provides a licensable option that adds the capability for fixed beam treatments from multiple user defined angles as well.

4.4 Safety Considerations

The HI-ART System has several inherent characteristics that promote its safety – no beam blocks are used that can fall off onto the patient; the rotating gantry is covered so that the patient cannot contact moving gantry parts; the linear accelerator operates in photon mode only so inadvertent electron exposure is eliminated; MVCT allows for reliable patient positioning. This modification introduces no new fundamental technical characteristics or safety concerns.

4.5 Standards Compliance

The HI-ART System is designed to comply with relevant sections of the IEC 60601-1, IEC 60601-2-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-32, IEC 60601-2-44, IEC 61217, EN ISO 14971:2007, and IEC TR 62266 safety standards.

4.6 Validation

The HI-ART System was extensively validated for system functionality, including planning, imaging, delivery, database management, DICOM communications, etc. Test tools utilized in this testing included IMRT phantoms, ion chambers and other test phantoms.

4.7 Conclusion

Validation and verification testing of the HI-ART System demonstrates the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2008

Mr. Robert Bovy
Director of Regulatory Affairs
TomoTherapy Incorporated
1240 Deming Way
MADISON WI 53717-1954

Re: K082005
Trade/Device Name: TomoTherapy HI-ART System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: July 8, 2008
Received: July 14, 2008

Dear Mr. Bovy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 3 Indications for Use Form

- 510(k) Number (if known) K082005
- Device Name: **TomoTherapy HI-ART System**
- Indications for use:

The TomoTherapy HI-ART System is intended to be used as an integrated system for the planning and precise delivery of radiation therapy, stereotactic radiotherapy, or stereotactic radiosurgery to tumors or other targeted tissues while minimizing the delivery of radiation to vital healthy tissue. The megavoltage x-ray radiation is delivered in a rotational, non-rotational, modulated (IMRT), or non modulated (non-IMRT/three dimensional conformal) format in accordance with the physician approved plan.

PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 810.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082005